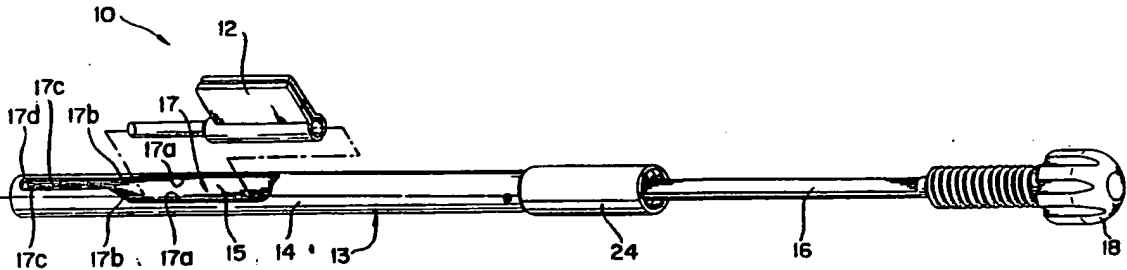


PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61F 2/16	A1	(11) International Publication Number: WO 94/07436 (43) International Publication Date: 14 April 1994 (14.04.94)
(21) International Application Number: PCT/US93/09255 (22) International Filing Date: 29 September 1993 (29.09.93) (30) Priority data: 07/953,251 30 September 1992 (30.09.92) US (71)(72) Applicant and Inventor: FEINGOLD, Vladimir [US/US]; 28636 Jaeger Drive, Laguna Niguel, CA 92677 (US). (74) Agent: KLIMA, William, L.; Crystal Plaza One - Suite 304B, 2001 Jefferson Davis Highway, Arlington, VA 22202 (US).		(81) Designated States: AT, AU, BB, BG, BR, CA, CH, DE, DK, ES, FI, GB, HU, JP, KP, KR, LK, LU, MG, MN, MW, NL, NO, PL, RO, RU, SD, SE, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: INTRAOCULAR LENS INSERTION SYSTEM  (57) Abstract A surgical device for implantation of deformable intraocular lens into the eye through a relatively small incision made in the ocular tissue including a holder with receiver for a lens holder. A lens holder (13) for a surgical device for implantation of deformable intraocular lens into the eye including a split tubular member (12) having a fixed tubular portion and a moveable tubular portion (68) connected together at a hinge (82). A method for implantation of deformable intraocular lens into the eye using the above-described surgical devices.		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NE	Niger
BE	Belgium	GN	Guinea	NL	Netherlands
BF	Burkina Faso	GR	Greece	NO	Norway
BG	Bulgaria	HU	Hungary	NZ	New Zealand
BJ	Benin	IE	Ireland	PL	Poland
BR	Brazil	IT	Italy	PT	Portugal
BY	Belarus	JP	Japan	RO	Romania
CA	Canada	KP	Democratic People's Republic of Korea	RU	Russian Federation
CF	Central African Republic	KR	Republic of Korea	SD	Sudan
CG	Congo	KZ	Kazakhstan	SE	Sweden
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovak Republic
CM	Cameroon	LU	Luxembourg	SN	Senegal
CN	China	LV	Latvia	TD	Chad
CS	Czechoslovakia	MC	Monaco	TG	Togo
CZ	Czech Republic	MG	Madagascar	UA	Ukraine
DE	Germany	ML	Mali	US	United States of America
DK	Denmark	MN	Mongolia	UZ	Uzbekistan
ES	Spain			VN	Viet Nam
FI	Finland				

INTRAOCULAR LENS INSERTION SYSTEM

Background of the Invention:

Field of the Invention:

5 This invention relates to a system including methods and devices for the surgical implantation of deformable intraocular lenses into the eye.

Prior Art:

10 Intraocular lenses have gained wide acceptance in replacement of human crystalline lenses after a variety of cataract removal procedures. The human crystalline lens is generally recognized to be a transparent structure having a thickness of about five (5) millimeters and a diameter of about nine (9) millimeters.

15 The lens is suspended behind the iris by zonula fibers which connect the lens to the ciliary body. A lens capsule surrounds the lens, the front portion of the capsule being commonly known as the anterior capsule and the back portion commonly known as the posterior capsule.

20 Numerous procedures for the removal of cataracts have been developed in which the lens is removed from the eye and replaced by an artificial lens implant. The extraction procedure may generally be categorized as intracapsular (in which the lens is removed together with

the lens capsule) and extracapsular (in which the anterior capsule is removed with the lens, and the posterior capsule is left intact).

5 Since Ridley implanted the first artificial lens in about 1949, the problems associated with cataract extraction and lens implantation have received a great deal of attention from ophthalmic surgeons. Various types of artificial lenses have been proposed, and appropriate surgical procedures have been developed which
10 strive to reduce patient discomfort and to reduce postoperative complications. Reference is made in this connection to Pseudophakos by N. Jaffe et al.; "History of Intraocular Implants" by D.P. Choyce (Annals of Ophthalmology, October 1973); U.S. Patent No. 4,251,887
15 issued to Anis on February 24, 1981; U.S. Patent No. 4,092,743 issued to Kelman on November 8, 1977; "Comparison of Flexible Posterior Chamber Implants", presented at the American Intraocular Implant Society Symposium April 23, 1982, by Charles Berkert, M.D.; and
20 "the Simcoe Posterior Lens" (Cilco, Inc. 1980); U.S. Patent No. 4,573,998 issued to Mazzocco on March 4, 1986, and U.S. patent application Ser. No. 400,665 for "Improved Fixation System for Intraocular Lens Structures", filed July 22, 1982, U.S. Patent No.
25 4,702,244 issued to Mazzocco on October 27, 1987; and U.S. Patent No. 4,715,373 issued to Mazzocco et al. on December 29, 1987, which disclosures are hereby incorporated by reference.

30 Of particular interest in the context of the present invention is the development of surgical techniques requiring relatively small incisions in the ocular tissue for the removal of cataracts as disclosed in U.S. Patent No. 4,002,169 and U.S. Patent No. 3,996,935. A number of

skilled artisans have disclosed intraocular lens structures comprising an optical zone portion generally made of rigid materials such as glass or plastics suitable for optical use.

5 However, one of the principal disadvantages of the conventional rigid intraocular lens is that implantation of the lens requires large incisions in the ocular tissue. This type of surgical procedure leads to a relatively high complication rate, among other
10 disadvantages. For instance, the serious dangers associated with implantation of a rigid lens structure include increased risk of infection, retinal detachment, and laceration of the ocular tissue, particularly with respect to the pupil.

15 Accordingly, those skilled in the art have recognized a significant need for surgical tools for implantation of deformable intraocular lens structures which afford the clinical advantages of using relatively small incision techniques, which provide a safer and more
20 convenient surgical procedure. In particular, those skilled in the art of deformable intraocular lenses and methods and devices for implantation, have also recognized a significant need for surgical tools which do not require widening of the wound made in the ocular
25 tissue during or after implantation, but will deform the intraocular lens to a predetermined cross section in a stressed state and which allow the ophthalmic surgeon to inspect the lens prior to implantation without manipulation in the eye. The present invention fulfills
30 these needs.

The present invention was derived by improving the methods and devices in the above-identified patents, specifically the methods of U.S. Patent No. 4,573,998 and the devices of U.S. Patent No. 4,702,244.

5

Summary of the Invention

An object of the present invention is to provide an improved system including methods and devices for surgical implantation of deformable intraocular lenses.

Another object of the present invention is to provide a surgical device including a lens holder, which can be loaded with a deformable intraocular lens, and then inserted into a holder having means for implanting the lens.

A further object of the present invention is to provide a surgical device including a lens holder define by a microcartridge comprising a lens holding portion in combination with a nozzle for implanting the lens.

A still further object of the present invention is to provide a lens holding microcartridge for receiving a lens comprising a split tubular member having a fixed portion with an extension, and a moveable portion with an extension for opening and closing the microcartridge, which extensions prevent rotation between the microcartridge and holder when installed in the holder.

An even further object of the present invention is to provide a lens holding microcartridge having a nozzle provided with slots for rotating the lens as it exits the nozzle.

An object of the present invention is to provide a surgical device including a lens holder and a holder for the lens holder, the holder comprising a receiver for the lens holder and a plunger for inserting the lens.

Another object of the present invention is to provide a holder defined by a cylindrical tubular member with an opening through the wall of the tubular member defining a receiver for the lens holder, and a plunger having a tip for contacting with and moving a lens contained in the lens holder.

A further object of the present invention is to provide a plunger with a faceted tip that provides clearance for a trailing haptic in a passageway through the lens holder during the implantation process to prevent damage to the trailing haptic.

An even further object of the present invention is to provide a plunger having a tip with a concave conical surface at the tip thereof for grabbing the lens during the implantation process.

An object of the present invention is to provide improved methods of implanting deformable intraocular lenses;

Another object of the present invention is to provide a method including loading a deformable intraocular lens into a lens holder having an implantation nozzle, condensing the intraocular lens within the lens holder, and implanting the lens into the eye.

The present invention concerns a system including methods and devices for implantation of intraocular lenses into the eye.

The surgical device according to the present invention includes the combination of a lens holder and a holder for the lens holder. The preferred lens holder comprises the combination of a lens receiver and an implantation nozzle. The lens receiver is preferably defined by a microcartridge comprising a split tubular

member having a fixed tubular portion with an extension connected to a moveable tubular portion with an extension at a hinge. This configuration allows the microcartridge to be opened to accept a deformable intraocular lens, and closed to condense the lens into the passageway. The split tubular portion is connected to a nozzle with a continuous passageway passing through the tubular member and the nozzle.

The lens holder is inserted into a holder having means for driving or manipulating the lens from the lens holder into the eye. In the preferred embodiment, the holder is provided with a plunger for driving the lens from the lens holder into the eye. Further, the holder is configured to receive a microcartridge having a nozzle.

The preferred holder includes means to prevent the microcartridge from rotating within the holder, and means for preventing the plunger from rotating within the holder. The means for preventing rotation of the microcartridge within the holder can be define by providing the microcartridge with one or more extensions that cooperate with the opening of the receiver of the holder to prevent rotation. The means for preventing the plunger from rotating within the holder can be defined by providing the plunger and a sleeve within the holder with a particular cross-sectional shape that prevents rotation, for example, a half-circle shape.

The preferred holder includes a plunger with a threaded cap cooperating with a threaded sleeve of the holder body for dialing the plunger forward within the holder for precise and accurate movement of the lens during the implantation process. The holder is configured so that the plunger can be moved a

predetermined distance by sliding motion within the holder body followed by engagement of the threaded cap of the plunger with the threaded sleeve of the holder body to continue the forward progress of the plunger tip.

5 The preferred plunger tip is defined by a faceted tip having various surfaces for moving and manipulating the lens from the lens holder and within the eye. The tip is designed to provide a clearance between the tip and the inner surface of the passageway through lens
10 holder to accommodate the trailing haptic and prevent damage thereto. Once the lens is inserted into the eye, the tip can be used to push and rotated the lens into proper position within the eye.

A method according to the present invention includes
15 lubricating the surface of a deformable intraocular lens with a surgically compatible lubricant, and loading the lens into a microcartridge in the opened position. The microcartridge is closed while condensing the lens by a folding action into a shape so that it can be forced
20 through the passageway in the microcartridge. The microcartridge is inserted into the holder with the plunger retracted.

The plunger is moved forward in a sliding manner by pushing the plunger forward while holding the holder body
25 still. This action forces the lens from the tubular member portion of the microcartridge into the nozzle portion. At this point the threads of the threaded end cap of the plunger engage with the threads of the threaded sleeve. The threaded end cap is rotate slightly
30 to engage the threads. The device is now ready for the implantation process.

The nozzle of the microcartridge is placed through a small incision in the eye. The threaded end cap of the plunger is rotated or dialed to further advance the lens forward through the nozzle and into the eye. The threaded end cap is further dialed to exposed the tip of the plunger within the eye and push the lens into position. The tip can be used to also rotate the lens within the eye for positioning of the haptics.

Brief Description of the Drawings

Figure 1 is a perspective view of one embodiment of device according to the present invention with a lens holding microcartridge positioned in the device for implantation of deformable lens structures for placement in the eye;

Figure 2 is a perspective view of the surgical device depicted in Figure 1 with the plunger retracted, and with the lens holding microcartridge removed;

Figure 3 is a side view of the device depicted in Figure 2, with the plunger in the extended position;

Figure 4 is a side elevational view of the device shown in Figure 1;

Figure 5 is a detailed longitudinal cross-sectional view of the device shown in Figure 4;

Figure 6 is a detailed transverse cross-sectional view of the device, as indicated in Figure 5;

Figure 7 is a detailed end view of the device, as indicated in Figure 5;

Figure 8 is an enlarged detailed left side elevational view of the tip of the plunger in the spacial orientation as shown in Figure 1;

Figure 9 is an enlarged detailed end view of the tip shown in Figure 8;

Figure 10 is an enlarged detailed top planar view of the tip of the plunger;

Figure 11 is an enlarged detailed right side elevational view of the tip of the plunger in the spacial orientation, as shown in Figure 4;

Figure 12 is an enlarged detailed bottom view of the tip of the plunger in the spacial orientation, as shown in Figure 1;

Figure 13 is a perspective view of a lens for use in the present invention;

Figure 14 is a perspective view of another type of lens for use in the present invention;

Figure 15 is a side view of the lens shown in Figure 13;

Figure 16 is a perspective view of the lens holding microcartridge in the open position to allow a lens to be loaded therein;

Figure 16A is another perspective view of the lens holding microcartridge in the open position;

Figure 17 is a rear end elevational view of the lens holding microcartridge in the open position;

Figure 18 is a front end elevational view of the lens holding microcartridge in the open position;

Figure 19 is a rear end elevational view of the lens holding microcartridge in the closed position;

Figure 20 is a front end elevational view of the lens holding microcartridge in the closed position;

Figure 20A is a detailed end view of the nozzle showing three (3) slots of different length equally spaced about the circumference of the tip;

Figure 20B is a detailed perspective view of the tip showing the three (3) slots of different length;

Figure 20C is a detailed side view showing the beveled tip;

Figure 21 is a top planar view of the lens holding microcartridge in the open position;

5 Figure 22 is a side elevational view of the lens holding microcartridge in the closed position;

Figure 23 is a rear end elevational view of the lens holding microcartridge in the closed position;

10 Figure 24 is a broken away side view of the device showing the lens holding microcartridge in relationship to the plunger in the retracted position;

Figure 25 is a broken away side view of the device showing the lens holding microcartridge in relationship to the plunger in a partially extended position;

15 Figure 26 is a broken away side view of the device showing the lens holding microcartridge in relationship to the plunger in a fully extended position;

Figure 27 is a perspective view showing the device positioning a deformable intraocular lens within the eye;

20 Figure 28 is a cross-sectional view of an eye showing the positioning of the deformable intraocular lens into position in the eye by the surgical device;

25 Figure 29 is a cross-sectional view of an eye showing the positioning of the deformable intraocular lens into a different position in the eye by the surgical device.

Figure 30 is a side elevational view of an alternative embodiment of the lens holding microcartridge provided with a beveled tip;

30 Figure 31 is a rear end elevational view of another alternative embodiment of the lens holding microcartridge provided with grooves in the passageway to facilitate folding the cartridge in an open position;

Figure 32 is a rear end elevational view of another alternative embodiment of the lens holding microcartridge provided with grooves in the passageway to facilitate folding the cartridge in a closed position;

5 Figure 33A is a front end elevational view of the nozzle of an alternative embodiment of the lens holding microcartridge; and

10 Figure 33B is a front end elevational view of the nozzle of a further alternative embodiment of the lens holding microcartridge.

Description of Preferred Embodiments

15 The present invention is directed to a system including methods and devices for implantation of deformable intraocular lens structures for surgical placement in the eye.

20 An inventive device according to the present invention comprises a holder having a receiver, a lens holder that can be removably inserted into the receiver of the holder, and means such as a moveable plunger disposed within the holder to force and manipulate the lens from the lens holder into the eye.

25 Preferably, the lens holder is defined by a lens holding microcartridge for receiving the lens structure. Further, the microcartridge is preferably a structure configured to be opened and closed. The preferred embodiment of the microcartridge receives a lens having prescribed memory characteristics when in the open position, and performs the function of folding or deforming the lens structure into a condensed configuration when being closed. Alternatively, the
30 microcartridge can be a structure having a passageway defined by a continuous walled annulus, and a lens could

be inserted into the passageway from the end of microcartridge by compressing, rolling, folding, or combination of these techniques prior to insertion into the microcartridge.

5 Once a lens is positioned into the microcartridge, the microcartridge is positioned into a plunger device. The assembled device maintains the lens in its condensed configuration during insertion into the eye yet permits the deformed lens to return to its original
10 configuration, size and fixed focal length once implanted in the eye, thereby providing a safe, convenient, and comfortable surgical procedure.

A preferred embodiment of a deformable intraocular lens implantation device 10 according to the present
15 invention is shown in Figures 1, 2 and 3. The implantation device comprises a microcartridge 12 disposed within a holder 13 comprising a holder body 14 with a receiver 15, and a moveable plunger 16. In Figure 1, the receiver 15 is defined by an opening 17 through
20 the wall of the holder body 14 of the size and shape shown in Figures 1 and 2. The opening 17 is defined by parallel edges 17a, 17a, which are sufficiently spaced apart to allow the microcartridge 12 to be loaded into the receiver 15 of the holder 13, tapered edges 17b, clamping edges 17c, and stop edge 17d. In Figure 1, the
25 microcartridge 12 is positioned in the receiver 15 between the clamping edges 17c with the plunger extending through the microcartridge 12 in a position, for example, after a lens implantation procedure.

30 In Figure 2, the lens holding microcartridge 12 is shown removed from the holder 13 with the plunger 16 in a retracted position for allowing the microcartridge 12 containing a loaded lens and its haptic to be inserted

13

within the holder 13. In Figure 3, the holder 13 is shown with the plunger 16 in the extended position without the microcartridge 12 for purposes of illustration of the components.

5 The plunger 16 is fitted with a threaded end cap 18 at one end, and fitted with a tip 20 at an opposite end. The threaded end cap 18 is provided with a plurality of grooves 22 to allow a person to tightly grip the cap 18 with his or her finger tips. The threaded end cap 18 is
10 received within a threaded sleeve 24 of the insert holder 14. The threaded end cap 18 can be a separate component attached to the insert holder 13, or integral therewith, as shown in the construction in Figure 5.

15 The plunger 16 is installed within the holder 13 in a manner to allow the plunger to be reciprocated therein. In the illustrated embodiment, the plunger 16 is supported for sliding movement within the holder 13 by
20 guide 26, as shown in Figures 5 and 6. The outer dimension of the guide 26 is approximately the same size as the inner dimensions of the holder 13 to allow the guide to be inserted within the insert holder. During
25 construction, the guide 26 is inserted within the holder 13, and locked into position by pin 28 inserted into a predrilled hole in both the wall of the holder 13 and guide 26.

30 The cross-sectional shape of the plunger 16 as well as the shape of the inner surface of the guide 26 are approximately a half-circle, as shown in Figure 6. This arrangement prevents the plunger 16 from rotating within the holder 13 to maintain the orientation of the tip 20 relative to the holder 13 during operation.

The threaded end cap 18 is connected to the plunger 16 in a manner to allow the threaded end cap 18 to be rotated relative to the plunger 16. For example, the left end of the plunger 16 (Figure 5) is provided with a threaded extension 30, which is secured to the threaded end cap 18 by a nut 32. Specifically, the threaded end cap 18 is manufactured with external threads 34 and a longitudinal center bore 36 that ends on the right side of the threaded end cap 18 leaving a wall 38.

The wall 38 is provided with a hole slightly larger than the outer diameter of the threaded extension 34 to allow the threaded end cap 18 to freely rotate on the plunger 16 while being secured to the end of the plunger 16. During construction, the nut 32 is inserted through the center bore 36 and threaded onto the extension 30 to secure the threaded end cap 18 to the plunger 16. A curved cap 40 is press fitted into the end of the center bore 36 to seal the center bore 36 to prevent debris from entering therein during use.

The details of the tip arrangement are shown in Figures 7 to 12. The plunger 16 is manufactured with an extension 42 supporting tip 20. The tip 20 structure provides means for inserting the deformable intraocular lens into the eye and manipulating the lens within the eye after the insertion step. For example, the tip 20 is faceted in the manner shown in the figures. Specifically, the left side of the tip 20 shown in Figure 8 is provided with a flat surface facet 42, conical surface 44, and cylindrical surface 46. The right side shown in Figure 11 is provided with a concave surface facet 50.

The end face of the tip 20 is designed to push the lens into position once inserted into the eye. For example, the end face is defined by a concave cylindrical surface 52 shown in Figure 8.

5 Suitable deformable intraocular lens for use in the present invention are shown in Figures 13 - 15. The deformable intraocular lens 54 shown in Figures 13 and 15 includes a lens body 56 with attachment means defined by a pair of haptics 58 each having one end anchored in the
10 lens portion 56 and a free end for attachment to the eye tissue. The deformable intraocular lens 60 shown in Figure 14 includes a lens body 62 and attachment means defined by a pair of lateral lobes 64 of the lens portion 62.

15 The details of the preferred lens holding microcartridge 12 are shown in Figures 16 - 20. The microcartridge 12 comprises a split tubular member 66 extending to a continuous tubular member 67 and an implantation nozzle 68. When the microcartridge is in a
20 closed position, a continuous circular or oval passageway of the same diameter extends through the split tubular member 66 through the continuous tubular member 67 and through the implantation nozzle 68. The microcartridge is preferably made of injection molded plastic such as
25 polypropylene. The split tubular member 66 is defined by a fixed portion 70 and a moveable portion 72. The fixed portion 70 is fixed relative to the implantation nozzle 68, and is defined by a tubular portion 74 and extension 72. The moveable portion 72 is moveable relative to the
30 fixed portion 70 for opening and closing the split tubular member 66. The moveable portion 72 is defined by a tubular portion 78 and extension 80. A hinge 82 is provided between the fixed portion 70 and moveable

portion 72. The hinge 82 is defined by reducing the thickness of the walls of the tubular portion 74 and 75 at the hinge 82, as shown in Figures 17, 18 and 19. The hinge 82 runs the length of the split tubular member 66 to allow the extension 76 and 78 to be split apart, or brought together to open and close, respectively, the split tubular member 66.

The tubular portion 78 of the moveable portion 72 is provided with a sealing edge 84, which is exposed when the lens holding microcartridge 12 is opened, as shown in Figure 16A, and seals with a similar sealing edge 86 (See Figures 17 and 21) of the continuous tubular member 67 when the lens holding microcartridge is closed.

The end of the tip 20 is provided with three (3) equally spaced slots 87a, 87b and 87c of different length provided about the circumference thereof, as shown in Figures 20A and 20B. The slot 87a positioned at the top of the tip 20 is the shortest, slot 87c on the right side of the tip 20 is the longest, and slot 87b on the left side is of medium length. The slots 87a, 87b, 87c cause the lens 54 to rotate as it exits the tip 20.

Other embodiments of the microcartridge 12 according to the present invention are shown in Figures 30-33.

The microcartridge shown in Figure 30 is provided with a beveled tip 94 to facilitate entry of the tip through the incision in the eye during implantation. The beveled tip 94 can be set at approximately forty-five (45) degrees relative to the passageway through the microcartridge 12.

The embodiment of the microcartridge shown in Figures 31 and 32 is provided with a set of grooves 96 provided inside the passageway therethrough. The grooves accommodate the edges of the lens being loaded into the

microcartridge to facilitate bending of the lens. Specifically, the edges of the lens are placed in the grooves 96 to prevent relative slippage of the edges with the inner surface of the passageway through the microcartridge when the microcartridge is being folded into the closed position.

The embodiments of the microcartridge shown in Figures 33A and 33B each have a nozzle 68' having an oval cross-section with slots 87' differently positioned as shown, respectively, again to facilitate entry through an incision in the eye. Alternatively, the cross-section can be two half circles set apart and connected together rather than oval.

The various features of the microcartridges shown in Figures 16-21 and 30-33 can be used in various combinations to achieve an optimum design for a particular application. However, all of these features are typically considered improvements of the basic combination.

The components of the device 10, except for the microcartridge 12, are preferably fabricated from autoclavable material such as stainless steel or from a disposable rigid plastic such as medical grade ABS or the like.

METHODS OF IMPLANTATION

The surgical procedure begins by coating the lens with a surgically compatible lubricant, and loading the lens into the microcartridge. For example, as shown in Figure 21, a lens 54 having a lens body 56, a leading haptic 58a is loaded into the microcartridge 12 while a trailing haptic 58b remains trailing outside the microcartridge in the manner shown. Specifically, the

lens 54 is loaded downwardly into the opened microcartridge 12 until it sits on the inner surfaces of the tubular portions 74 and 78, for example, with a pair of tweezers. The outer circumferential surface of the lens 54 are held by edges 88 and 90 of the tubular portions 74 and 78, respectively. The rear edge of the lens 54 is placed approximately at the rear edge of the microcartridge 12. The lens 54 is further manipulated to situate the haptics 58a and 58b in the manner shown. Specifically, haptic 54a is positioned in a leading position and the other haptic 54b is positioned in a trailing position outside with respect to the direction of implantation, as indicated by the arrow.

Subsequently, the split tubular member 66 of the microcartridge 12 is closed about the lens 54 by forcing the extensions 76 and 80 together with his or her finger tips. The inner surfaces of the tubular portions 74 and 78 bend and fold the lens 54 when the extensions 76 and 80 are forced together, as shown in Figures 22 and 23. Due to the resilient nature of the deformable intraocular lens 54, the lens 54 conform to the curved inner surface of the tubular portions 74 and 78 without damage thereto, as shown in Figure 23.

The microcartridge 12 containing the loaded lens 54 is inserted between the edges 17a, 17a of the opening 17 into the receiver 15 of the holder 13. As the microcartridge 12 is moved forward, the extensions 76 and 80 move past the tapered edges 17b and come to a stop position between the clamping edges 17c when front portions of the extensions 76 and 80 contact with the stop edge 17d. The clamping edges 17c prevent rotation of the microcartridge inside the holder 13.

The user pushes the threaded end cap 18 forward while securing the holder body 14 from movement, forcing the plunger 16 forward within the holder. As the plunger 16 is moved forward, the tip 20 enters into the rear of the microcartridge 12 and misses the trailing haptic 58B until the tip makes contact with the loaded lens 54, as shown in Figure 24. As the plunger 16 is moved forward in this manner, the lens 54 previously lubricated, is forced into the implantation nozzle 68 of the microcartridge 12, as shown in Figure 25.

Once the lens 54 enters the implantation nozzle 68, the threads of the end cap 18 contact with the threads of the sleeve 24 stopping further movement of the plunger 14 forward in this manner. The end cap 18 is slightly rotated to engage the threads of the end cap 18 with the threads of the sleeve 24. At this point, the surgical device is ready for the implantation step. The nozzle is insert through the incision in the eye, and the end cap 18 is rotated to continue the forward movement of the plunger 16 by continued rotation of the end cap 18 relative to the holder body 14 to expel the lens from the nozzle into the interior of the eye, as shown in Figure 26. This manner of screw advancement for moving the plunger 16 forward provides for precise control and accuracy concerning forcing the lens 54 through the remaining portion of the tip 68 into the eye during the implantation procedure. The deformed lens after exiting the nozzle 16 returns to its original configuration, full size and fixed focal length.

After the lens is inserted into the eye, the end cap 18 is further rotated to fully expose the tip 20 of the plunger 16, as shown in Figures 28 and 29, to allow the lens to be pushed forward, side manipulated to rotate the

lens, and pushed down to properly position the lens within the eye without the aid of other surgical instruments.

5 The configuration of the tip 20 is important during the implantation process. The faceted tip 20 provides a clearance between the tip 20 and the inner surface of the passageway through the microcartridge 12 to accommodate the trailing haptic 58b during movement of the lens within the microcartridge 12, as shown in Figures 25 and 10 26. Specifically, there exists a sufficient clearance between the flat surface facet 44 and the inner wall of the passageway through the microcartridge 12. During the implantation process, the trailing haptic floats around in the space between the extension 42 of the tip 20 and 15 the inner wall of the passageway, as shown in Figure 25. This prevents any chance of damage to the trailing haptic, for example, by being caught between the tip 20 and the lens 54 during the implantation process. The leading haptic moves through the passageway unimpeded 20 during the implantation process preventing any damage thereto.

I CLAIM:

1. A surgical device for implantation of a deformable intraocular lens into the eye through a relatively small incision made in the ocular tissue, comprising:

a holder having a receiver at one end of said holder;

a moveable plunger disposed within said holder;

a lens holder having a nozzle portion with a tip for insertion through the incision in the ocular tissue, said lens holder having said nozzle portion is removably disposed within said receiver of said holder,

whereby a lens to be implanted is loaded into said lens holder, said lens holder is inserted into said receiver of said holder, and said plunger is actuated to implant said lens from said lens holder through said nozzle portion into the eye.

2. A device according to Claim 1, wherein said lens holder and said nozzle portion define a one piece structure.

3. A device according to Claim 2, wherein said nozzle portion includes a tapered end for facilitating entry of said nozzle portion through the incision in the ocular tissue.

4. A device according to Claim 2, wherein said lens holder is configured to open for loading a lens into said lens holder, and close for inserting said lens holder into said holder having said receiver.

5. A device according to Claim 4, wherein said lens holder is configured to deform the lens when closing to condense the configuration of the lens to pass through said nozzle portion for implanting the lens through the incision in the ocular tissue.

6. A device according to Claim 5, wherein the lens is placed into a curved folded configuration within a passageway in said lens holder leading to said nozzle portion when said lens holder is closed.

7. A device according to Claim 6, wherein said lens holder comprises a split tubular member defining said passageway and connected to said nozzle portion, wherein said split tubular member can be opened to insert the lens and closed to insert said lens holder into said holder.

8. A device according to Claim 7, wherein said split tubular member is defined by a fixed tubular portion relative to said nozzle portion, and a moveable tubular portion connected together at a hinge.

9. A device according to Claim 8, wherein said fixed tubular portion includes an extension and said moveable tubular portion includes an extension, wherein said extensions are moved apart to open said lens holder for loading the lens and moved together to fold the lens in the lens holder.

10. A device according to Claim 9, wherein the lens holder is made of disposable surgically acceptable plastic.

11. A device according to Claim 1, wherein said receiver is defined by a cylinder having an open end, an opening into said cylinder through a side wall thereof, and wherein said holder includes a threaded coupler at an end opposite said end having said receiver.

12. A device according to Claim 11, wherein said holder having said receiver is provided with a guide for slidably supporting said plunger for movement within said holder having said receiver.

13. A device according to Claim 12, wherein said guide and said plunger are configured to prevent relative rotation between said plunger and said holder having said receiver during movement of said plunger within said holder having said receiver during operation.

14. A device according to Claim 13, wherein said plunger includes an end cap with a threaded coupler cooperating with said threaded coupler of said holder having said receiver for moving said plunger within said holder having said receiver once said threaded couplers are engaged.

15. A device according to Claim 14, wherein said holder having said receiver and said plunger are configured to allow said plunger to move within said holder having said receiver a predetermined distance prior to engagement with said threaded couplers, wherein further movement of said plunger within said holder having said receiver is accomplished by rotating one threaded coupler relative to the other.

16. A device according to Claim 15, wherein said threaded coupler of said holder having a receiver is defined by a threaded sleeve, and said threaded coupler of said plunger is defined by a threaded end cap.

17. A device according to Claim 1, wherein a cross section of said nozzle portion is one selected from the group of circular, oval and two half circles set apart and connected together.

18. A device according to Claim 1, wherein said plunger is provided with a faceted tip for contacting and forcing the lens from the lens holder during the implantation operation, and for manipulating the lens into position within the eye.

19. A device according to Claim 18, wherein said faceted tip is defined by a conical surface extending from said plunger to a cylindrical surface, one side of said tip being provided with a flat or concave surface facet and an opposite side of said tip being provided with a flat or concave surface facet, and an end of the tip being provided with a concave surface groove for engaging a portion of the edge of the lens.

20. A surgical device for implantation of deformable intraocular lens into the eye through a relatively small incision made in the ocular tissue, comprising:

a holder having a receiver;

a lens holder having a nozzle portion with a tip for insertion through the incision in the ocular tissue, said lens holder having said nozzle portion is removably disposed as a unit within said receiver of said holder; and

means for manipulating said lens from said lens holder through said nozzle portion into the eye,

whereby a lens to be implanted is loaded into said lens holder, said lens holder is inserted into said holder having said receiver, and said manipulating means is actuated for directing and implanting the lens from said lens holder into the eye.

21. A lens holder for use with a surgical device for implantation of a deformable intraocular lens into the eye through a relatively small incision made in the ocular tissue, said lens holder comprising:

a nozzle portion with a tip configured for insertion through the incision in the ocular tissue;

a split tubular member having a passageway and connected to said nozzle portion, said split tubular member including a fixed tubular portion relative to said nozzle portion connected to a moveable tubular portion relative to said nozzle portion at a hinge;

an extension of said fixed tubular member; and

an extension of said moveable tubular member.

22. A lens holder according to Claim 21, wherein said hinge is defined by decreasing the wall thickness at joint between said fixed tubular portion and said moveable tubular portion.

23. A lens holder according to Claim 22, wherein said nozzle portion is provided with a beveled tip.

24. A lens holder according to Claim 23, wherein said tip of said nozzle portion is provided with slots.

25. A lens holder according to Claim 21, wherein said split tubular member is provided with grooves in the passageway therethrough to facilitate folding of the lens being loaded.

26. A method of implanting a deformable intraocular lens into the eye through a relatively small incision made in the ocular tissue, comprising the steps of:

loading the lens into a lens holder;

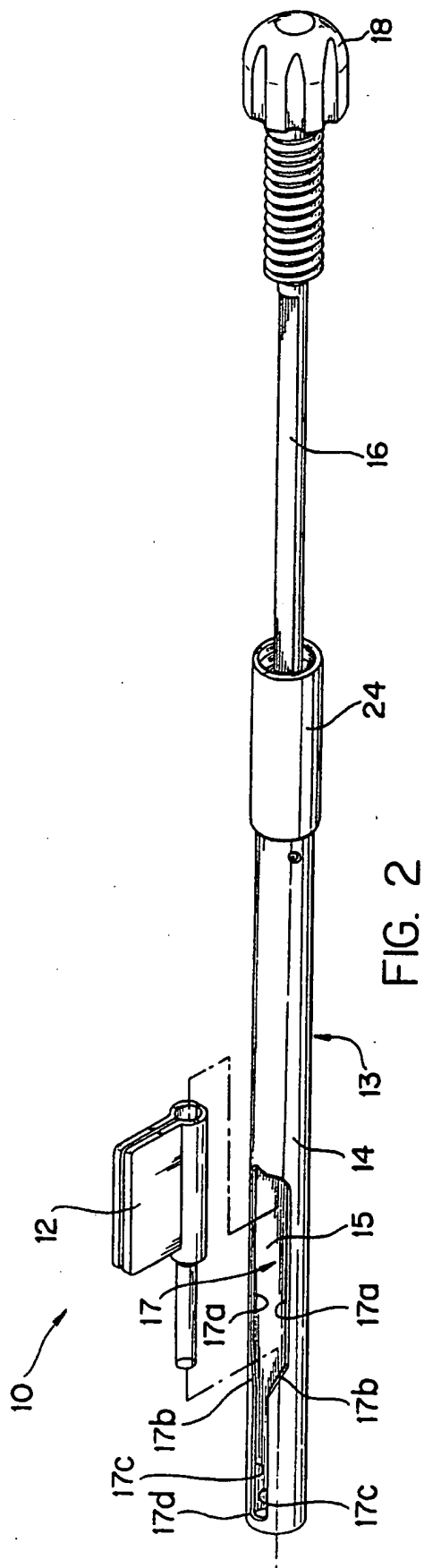
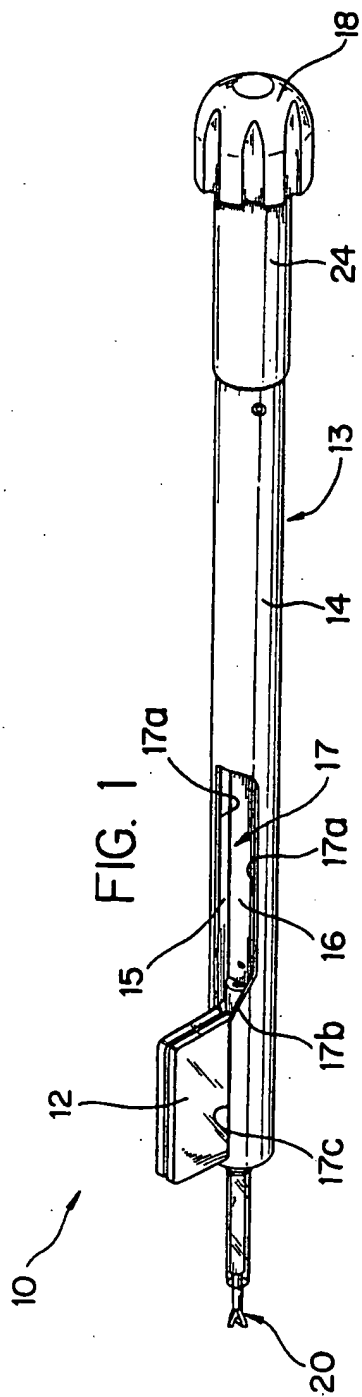
inserting the lens holder into a surgical device having means for moving and directing the lens from the lens holder through the ocular tissue into the eye, and means for manipulating the lens within the eye; and

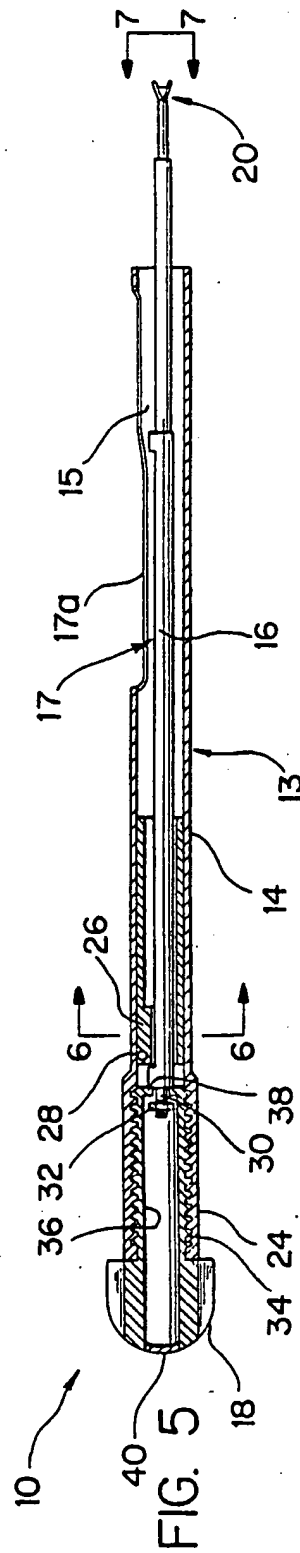
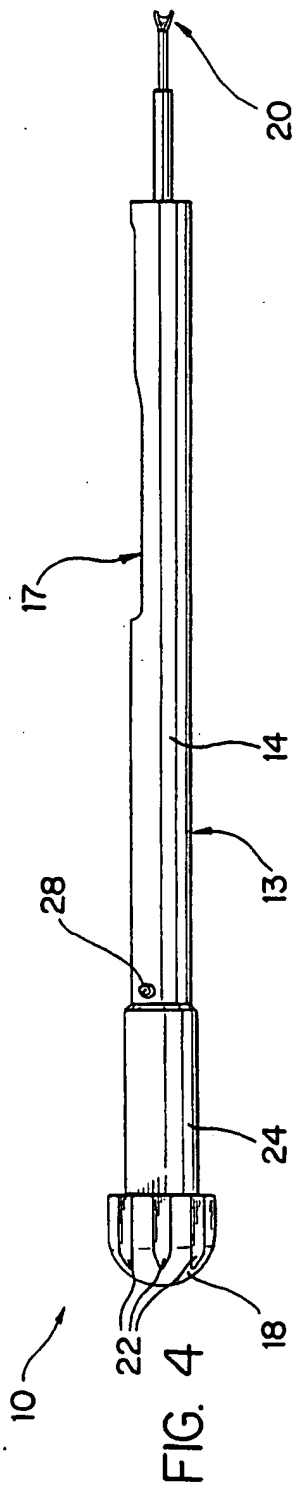
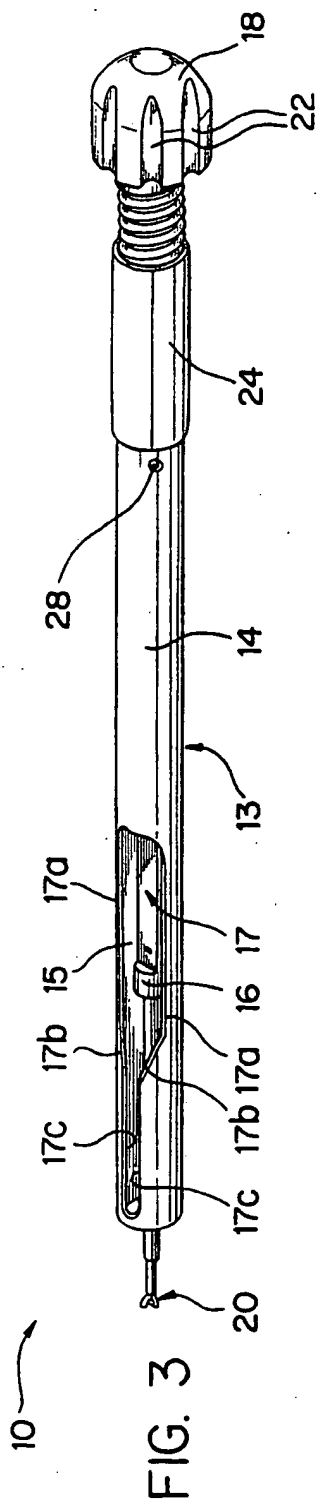
implanting the lens from the lens holder into the eye.

27. A method according to Claim 26, wherein said surgical device includes means for manipulating the lens within the eye, including the step of manipulating the lens with the surgical device into proper position within the eye.

27

28. A method according to Claim 26, wherein the lens includes a trailing haptic when loaded into said lens holder, and said trailing haptic is placed trailing outside said lens holder when said lens holder is loaded into said surgical device.





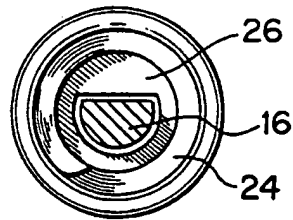


FIG. 6

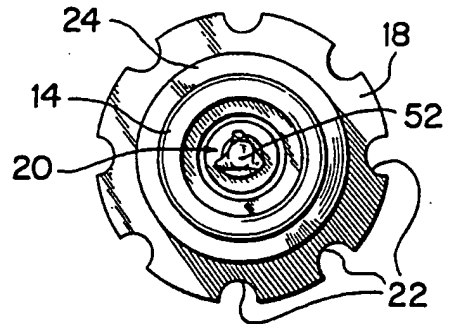


FIG. 7

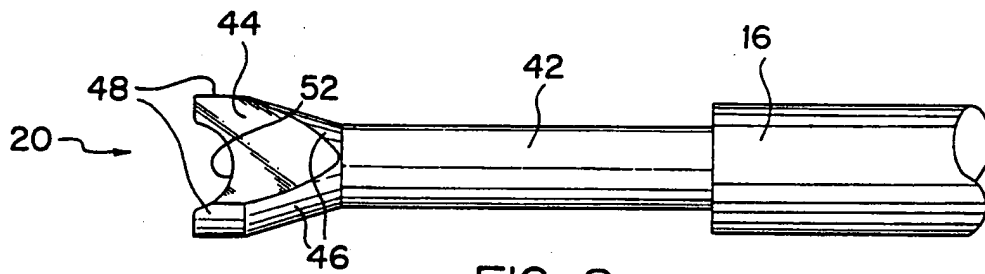


FIG. 8

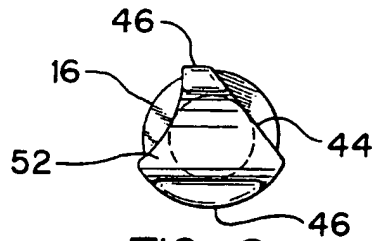


FIG. 9

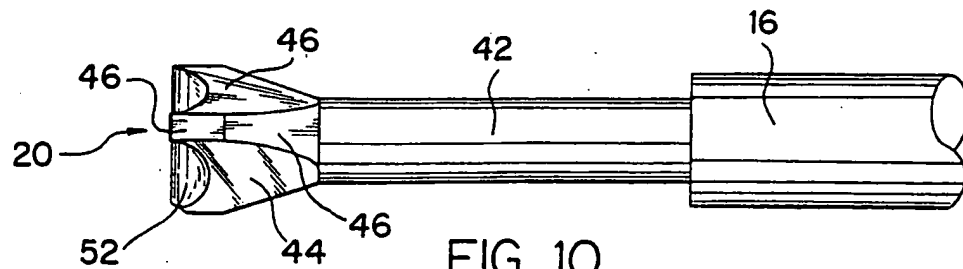
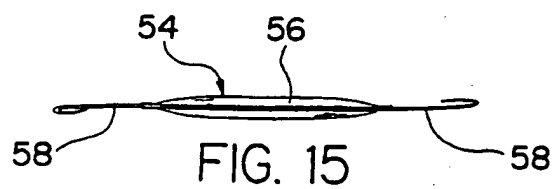
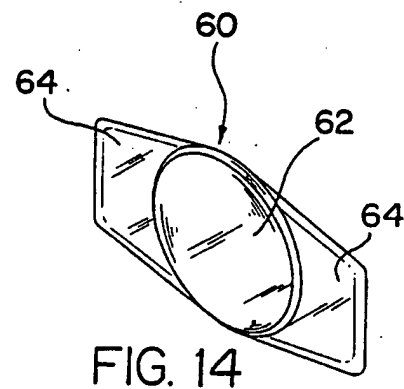
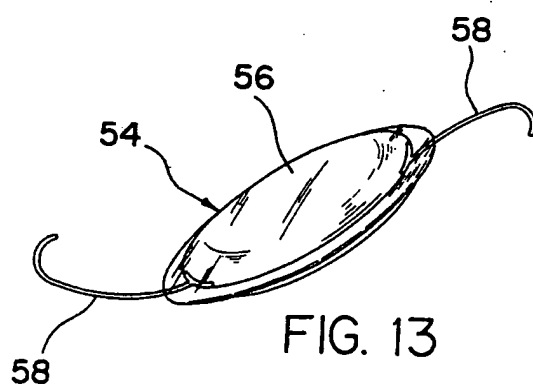
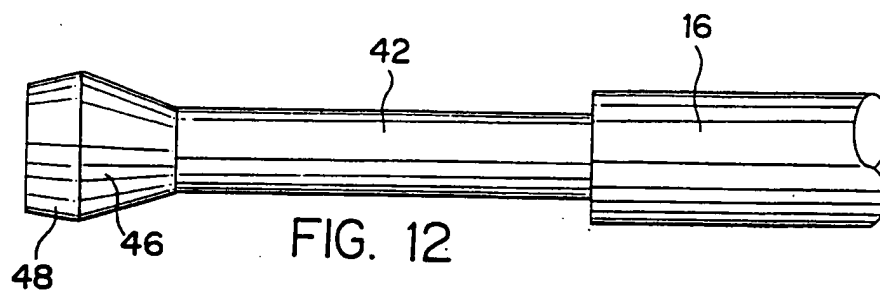
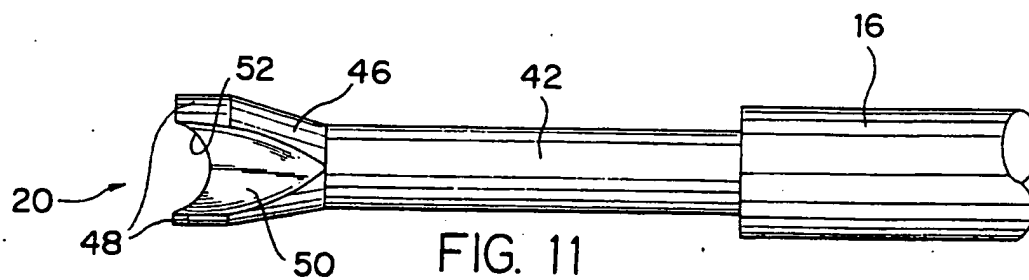
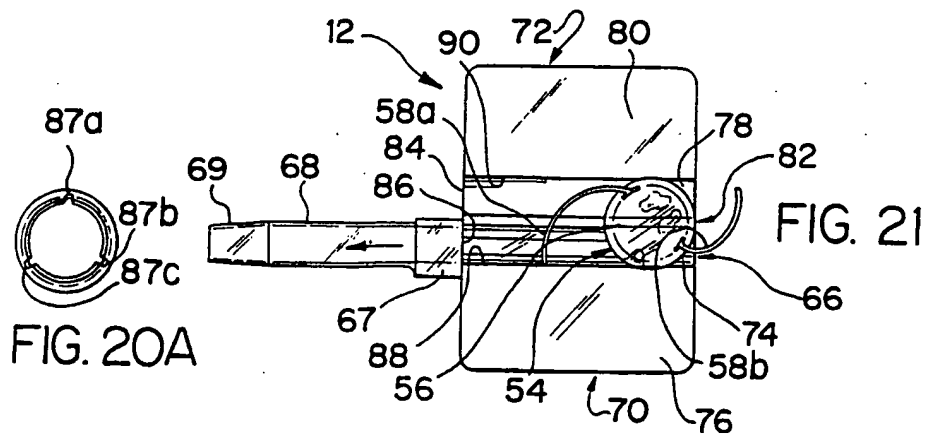
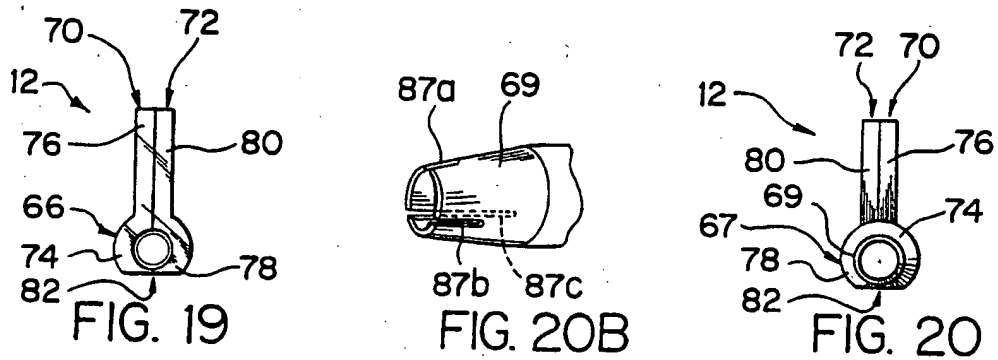
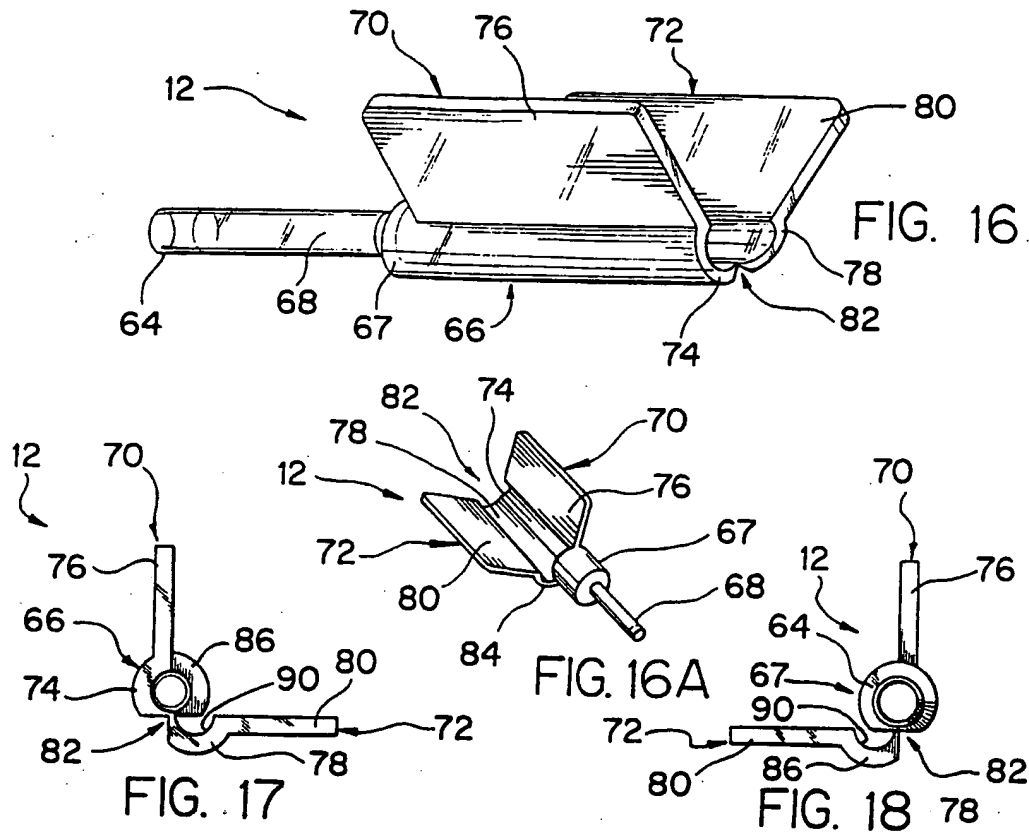
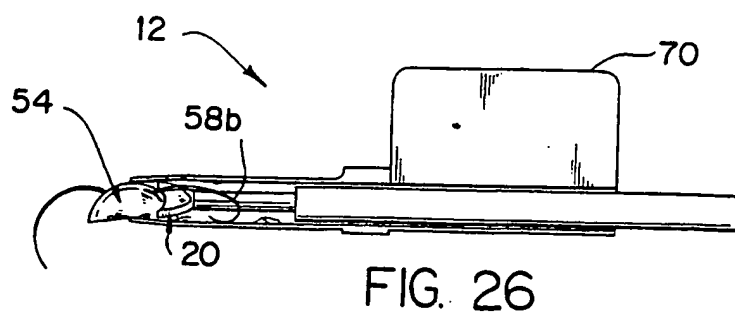
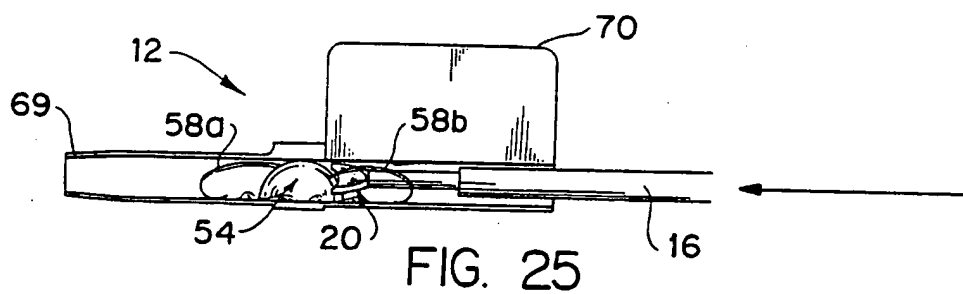
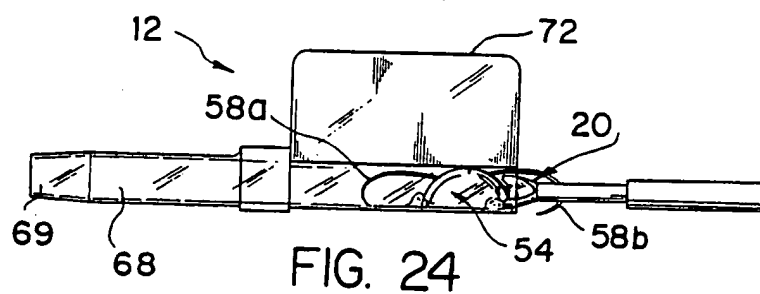
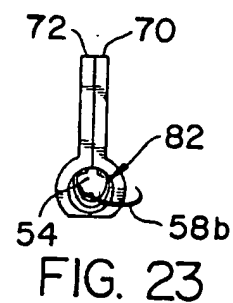
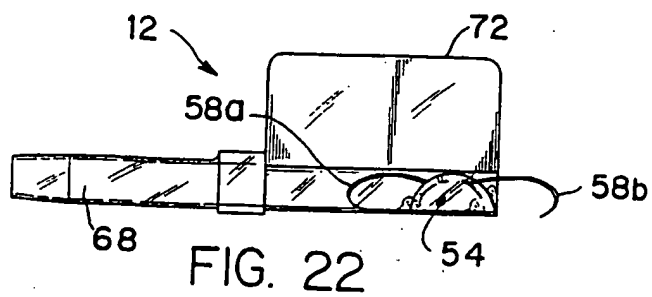


FIG. 10







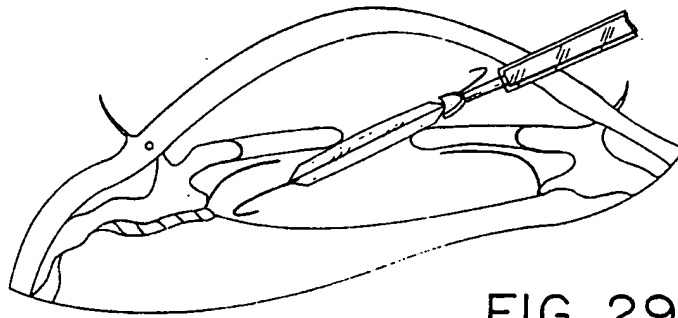


FIG. 29

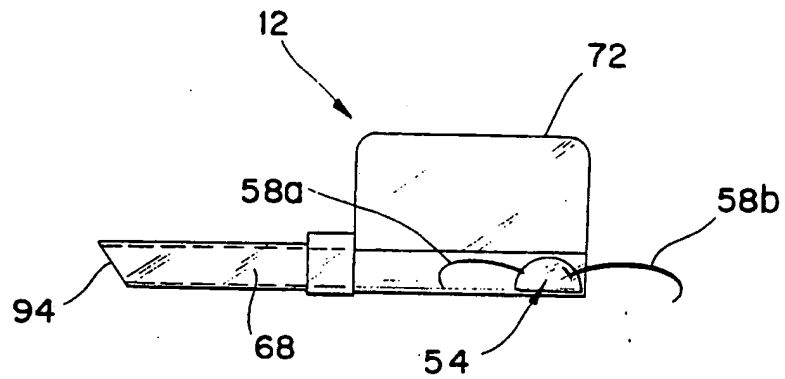


FIG. 30

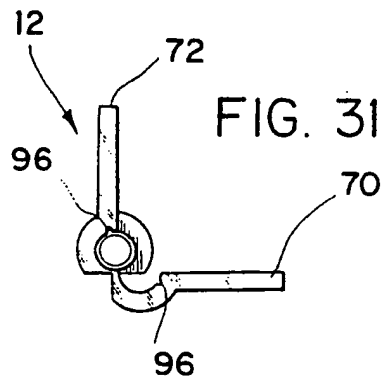


FIG. 31

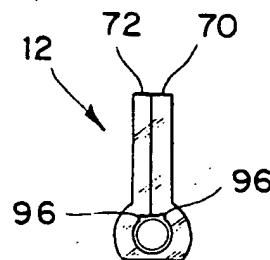


FIG. 32

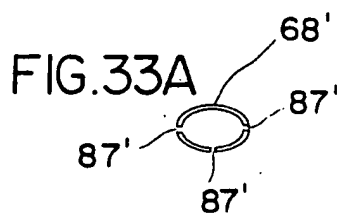


FIG. 33A

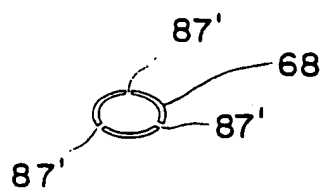


FIG. 33B

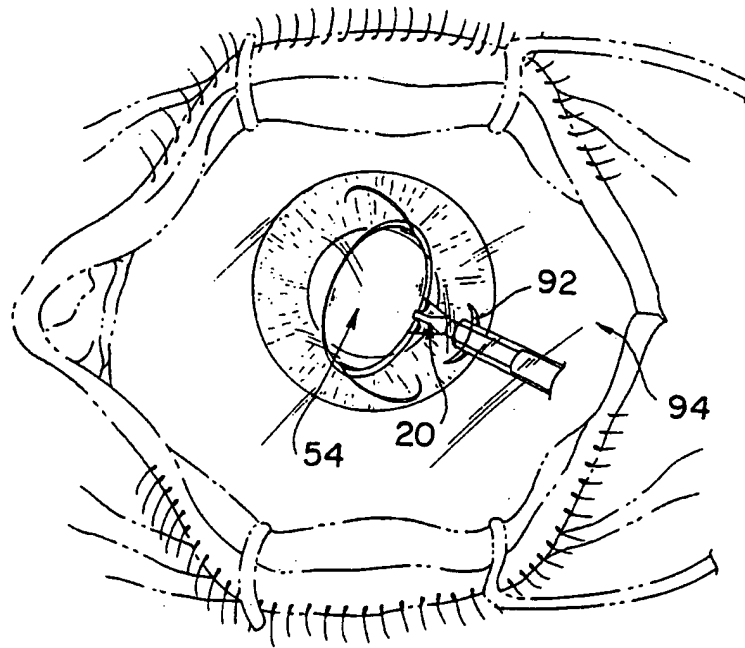


FIG. 27

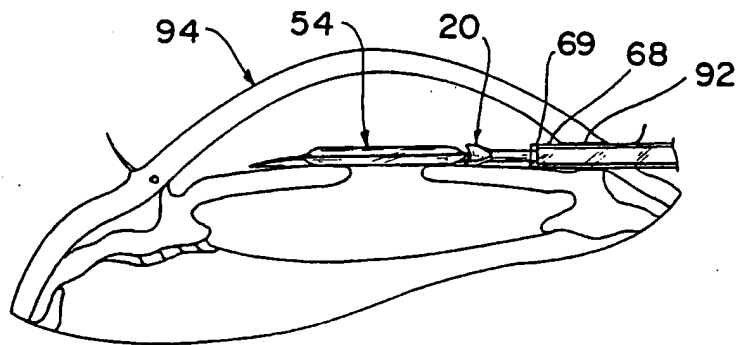


FIG. 28

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/09255

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61F 2/16

US CL :606/107

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/6; 206/5.1; 606.107

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
None

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
None

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,681,102 (Bartell) 21 July 1987. See Figs. 2 and 3.	26-28
A	US, A, 4,934,363 (Smith et al.) 19 June 1990. See Fig. 1.	1-28
A, P	US, A, 5,276,686 (Poley) 05 January 1993. See Fig. 3.	1-28

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be part of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A*	document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means		
P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

29 NOVEMBER 1993

Date of mailing of the international search report

MAR 14 1994

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Authorized officer

MARY BETH JONES

Facsimile No. NOT APPLICABLE

Telephone No. (703) 308-0858